Health Canada Santé Canada

Post Marketing data of Cox-2 Inhibitors

Dominique Heon M.D. FRCPC
A / Manager, Marketed Pharmaceuticals Division
Marketed Health Products Directorate

Health Products and Food Branch
Direction générale des produits de santé et des aliments

Data gathering

- 4 drugs: Rofecoxib, Celecoxib, Valdecoxib, Meloxicam*
- International: Periodic Safety Update Reports (PSUR)
- Domestic: Canadian Adverse Drug Reaction Monitoring Program (CADRMP)

*partially selective

Reporting rate: Purposes and Limitations

- Purposes:
  - Temporal signal follow-up
  - Compare drugs with the same indications
- Limitations:
  - Under reporting
  - Background noise
  - Awareness
  - Duration on the market
  - Seriousness

WHO seriousness criteria

- *A serious adverse event (experience) is an untoward medical occurrence that at any dose:*
  - *results in death,*
  - *is life-threatening,*
  - *requires inpatient hospitalisation or prolongation of existing hospitalisation,*
  - *results in persistent or significant disability/incapacity,*
  - *is a congenital anomaly/birth defect.*

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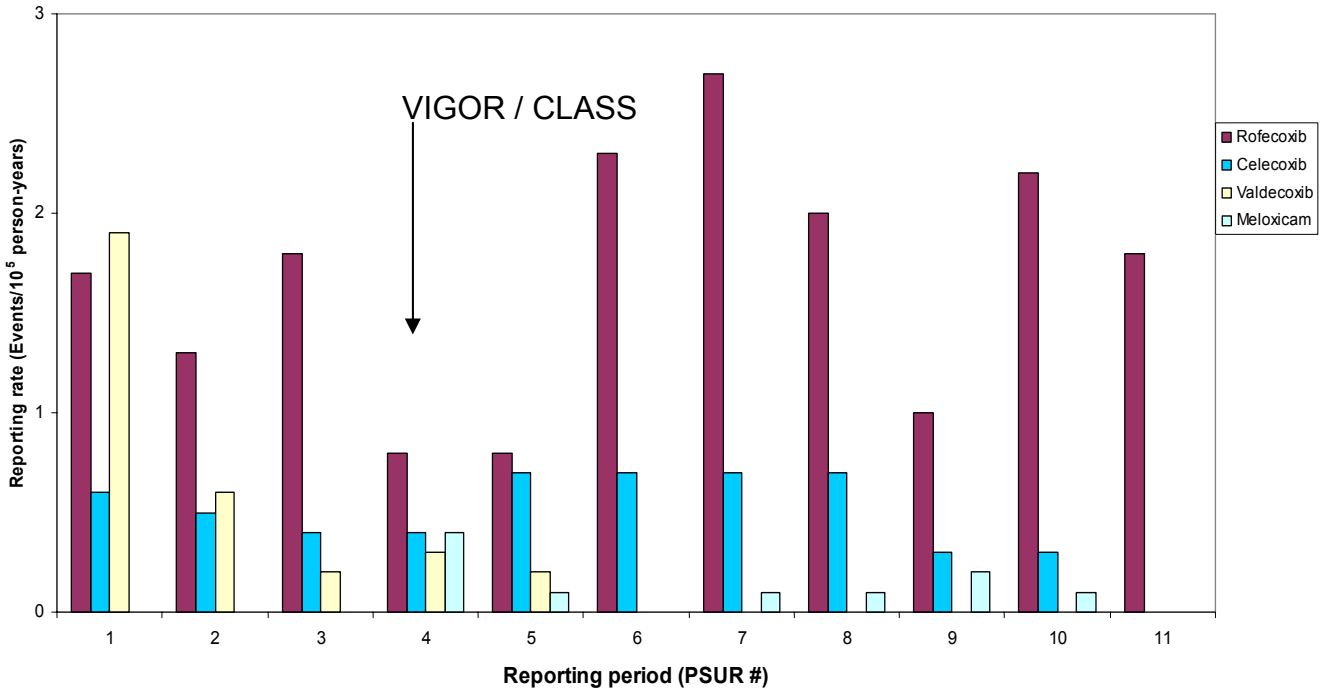
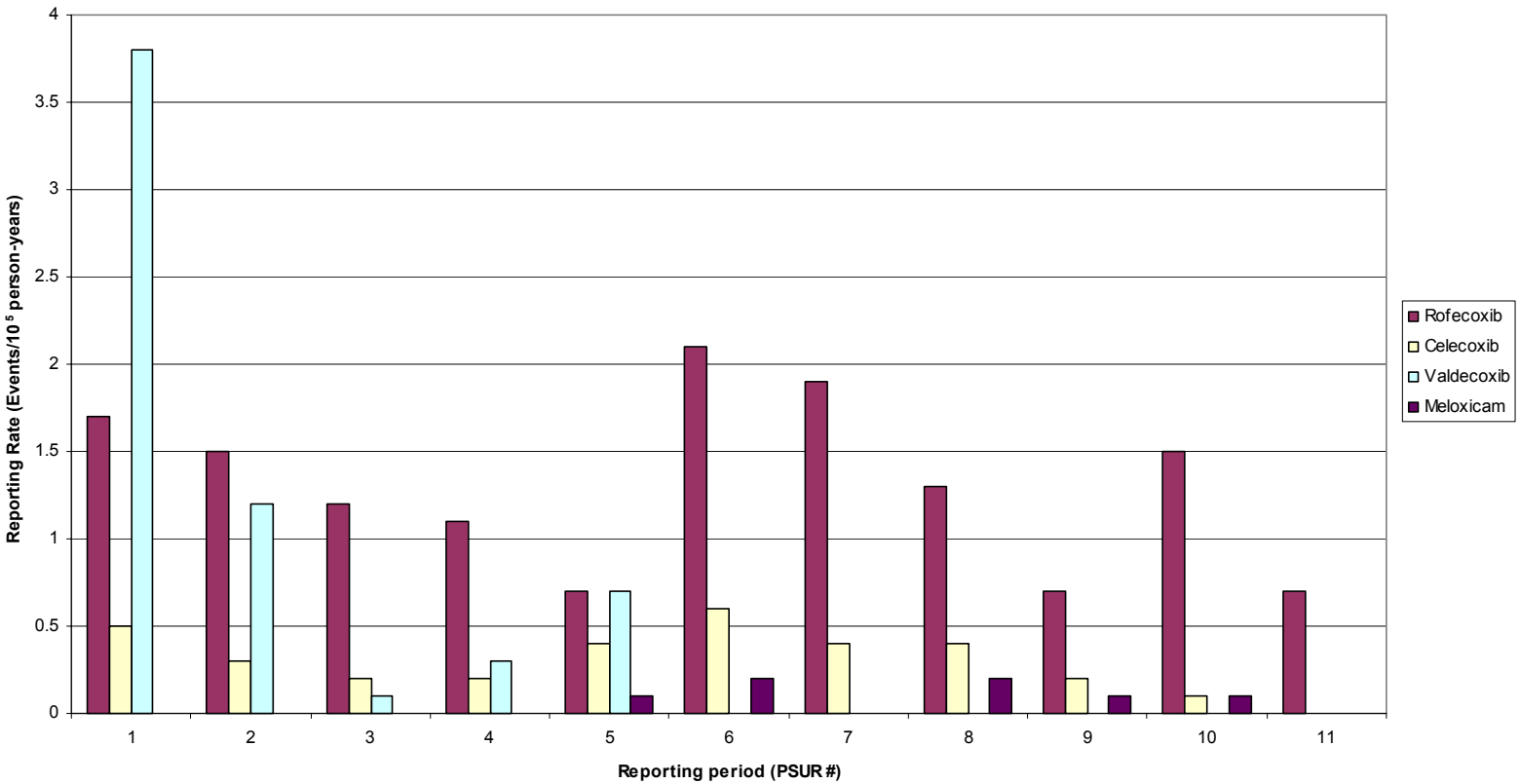
Canadian Adverse Drug Reaction Monitoring Program standard caveat

This summary is based on information from adverse event reports submitted by health professionals and laypersons either directly to Health Canada or via market authorization holders. Each report represents the suspicion, opinion or observation of the individual reporter. The Canadian Adverse Drug Reaction Monitoring Program is a spontaneous reporting system that is suitable to detect signals of potential health product safety issues during the post-market period. The data has been collected primarily by a spontaneous surveillance system in which adverse reactions to health products are reported on a voluntary basis. Under reporting of adverse reactions is seen with both voluntary and mandatory spontaneous surveillance systems. Accumulated **case reports should not be used as a basis for determining the incidence of a reaction** or estimating risk for a particular product as neither the total number of reactions occurring, nor the number of patients exposed to the health product is known. Because of the multiple factors that influence reporting, quantitative comparisons of health product safety cannot be made from the data. Some of these factors include the length of time a drug is marketed, the market share, size and sophistication of the sales force, publicity about an adverse reaction and regulatory actions. In some cases, the reported clinical data is incomplete and there is not certainty that these health products caused the reported reactions. A given reaction may be due to an underlying disease process or to another coincidental factor. This information is provided with the understanding that the data will be appropriately referenced and used in conjunction with this caveat statement. (12/2003)

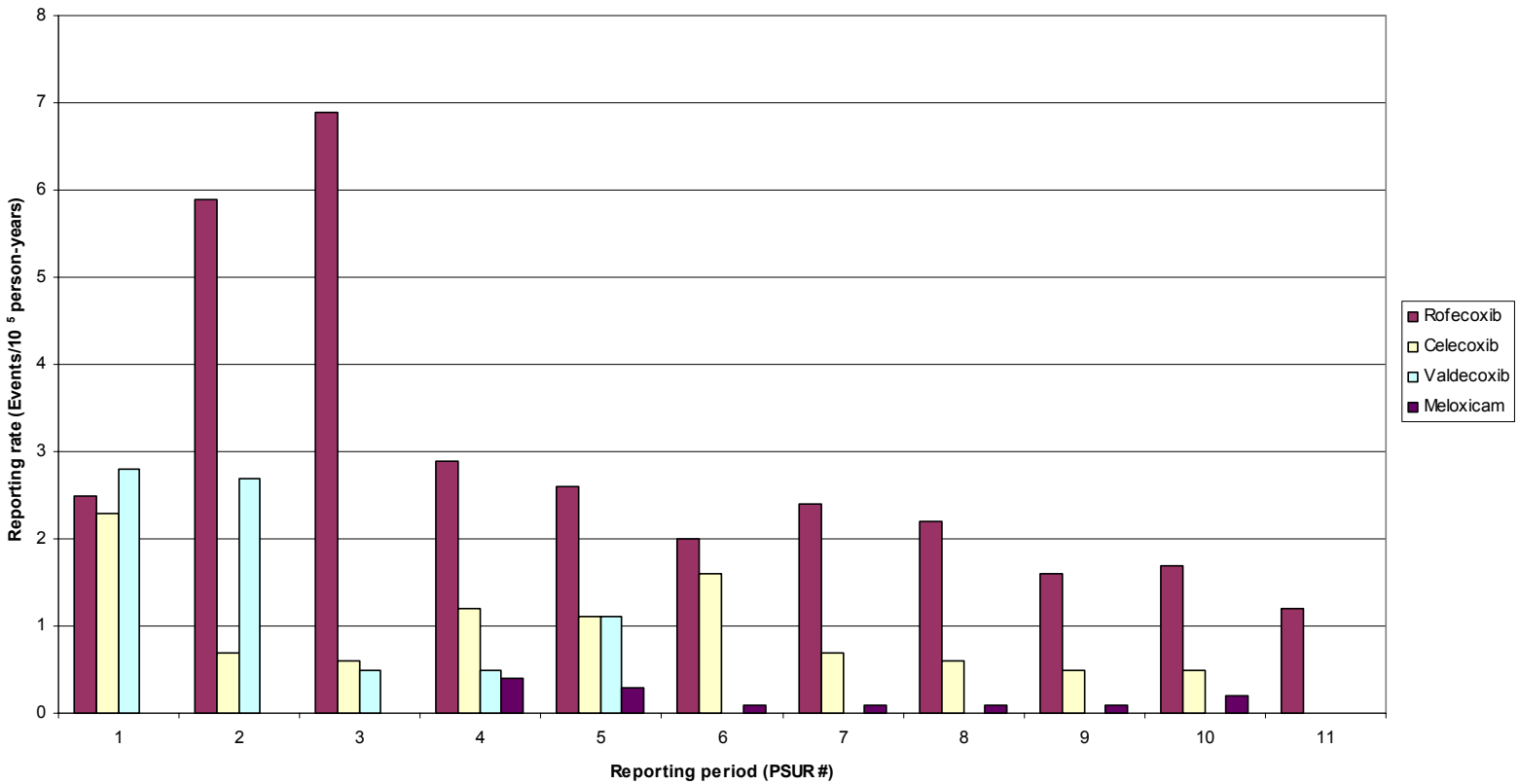
International reporting rate for myocardial infarction 1996-2004



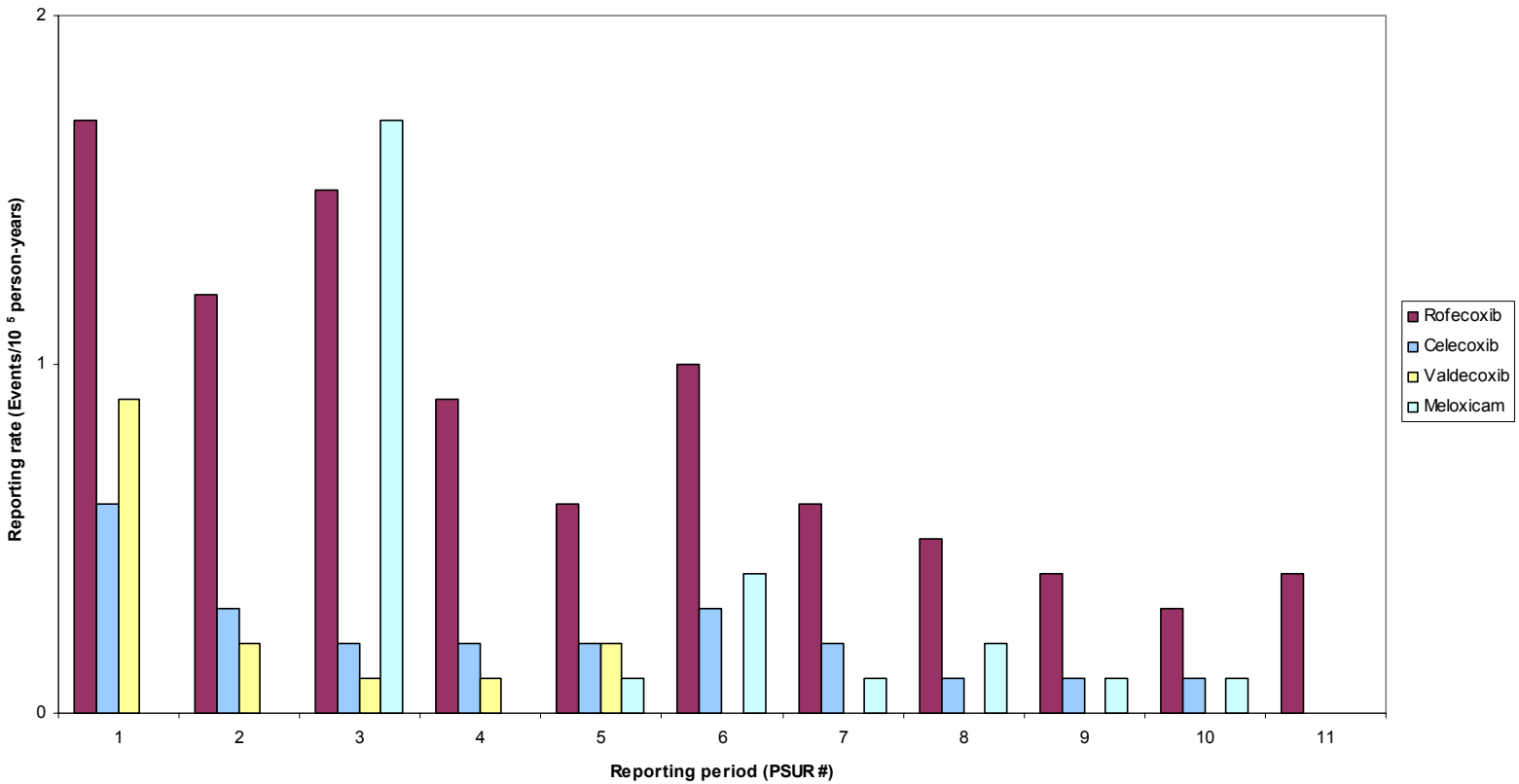
International Reporting rate for cerebrovascular accidents 1996-2004



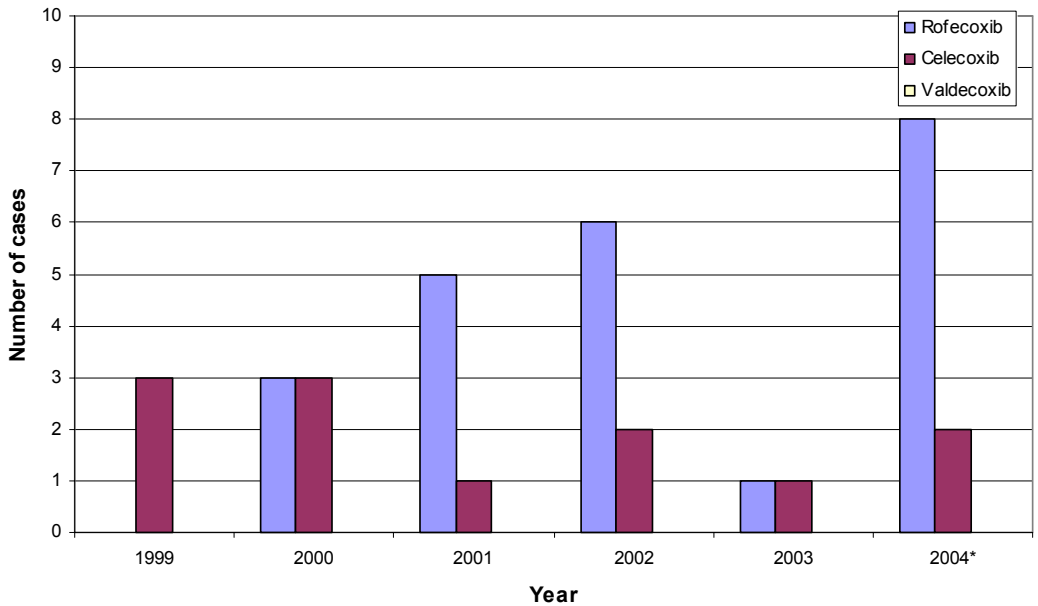
International reporting rate for cardiac failure 1996-2004



International reporting rate for cardiac death and arrest 1996-2004



Absolute number of myocardial infarction among users in Canada 1999-2004



Absolute number of cardiac failure among users in Canada 1999-2004